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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,746	10/14/2003	Reid M. Rubsamen	AERX-080CIP2	6142

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/685,746	RUBSAMEN ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-18 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 01/04 & 03/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-10 recite the limitation "the desired effect" in claims 1 or 7. There is insufficient antecedent basis for this limitation in the claim. Neither claims 1 or 7 recite or support the term "desired effect".

Claim 8 recites the limitation "sildenafil" in claims 1 or 7. There is insufficient antecedent basis for this limitation in the claim. Claim 7 does not contain and does not support the term "sildenafil".

NOTE: Claim 8 also contains a typographical error. The term sildenafil is incorrectly spelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-13, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by

Radhakrishnan et al (4,895,719).

Radhakrishnan et al teach method and apparatus for administering dehydrated liposomes by inhalation. Inhalation is to the respiratory system and formulations comprise one or more active agent, and propellants. The formulations may be in a liquid, suspension form or dehydrated powder form (see col. 4, lines 56-67). An example of medicaments used in the said formulation which can act systemically is oxytocin, a peptide hormone. Aerosols of liposome-oxytocin formulation would provide immediate and sustained delivery to the systemic circulation (see col. 16, lines 44-57).

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 5, 7-10, 14-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Rabinowitz et al (6,803,031 B2).

Rabinowitz et al disclose a delivery of erectile dysfunction drugs through an inhalation route. The particles are typically in the size range of less than 2 microns and the drugs typically are selected from the group consisting of sildenafil, tadalafil or vardenafil. The formulations result in a peak plasma concentration being reached in less than 0.2, 0.1, 0.05, 0.02, 0.01 or 0.005 hour (see col. 4, lines 5-10, 23-47 and claims 1-2). The inhalation device comprising the said formulation for delivery to patients for treating Erectile Dysfunction is described in columns 9-10.

Claims 7-13, 15-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Blood et al (6,579,968 B1).

Blood et al teach compositions and methods for treatment of sexual dysfunction. One object of the invention is to provide a peptide-based melanocortin receptor-specific pharmaceutical for use in treatment of male sexual dysfunction, including erectile dysfunction. One such drug is Melanotan-II (col. 4, lines 15-17, 26-31). Intrapulmonary or nasal administration can be achieved by using either a solution or a dry powder formulation. The pulmonary administration uses a metered dose inhaler or a device allowing self-administration of a metered bolus of a peptide of this invention (see col. 7, line 62 to col. 8. line 5, and lines 36-57). Fig. 5 shows that the formulations typically reach peak plasma levels in less than 30 minutes.

Claims 7-13, 15-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Staniforth et al (US 20040204440).

Staniforth et al teach a composition, device and method of treating sexual dysfunction via inhalation which comprises inhaling a dose of from about 100 to about 1600 micrograms apomorphine (a dopamine receptor agonist) or pharmaceutically acceptable salt or ester thereof (see abstract and [0012]). Staniforth also discloses a method of treating sexual dysfunction which comprises inhaling a dose of apomorphine or a pharmaceutically acceptable salt or ester thereof, said dose being sufficient to provide a therapeutic effect in about 10 minutes or less (see [0013] and [0093]).

The suitable formulation is in powder form and is delivered via a dry powder inhaler (DPI), but it may also be in a solution or suspension form inhaled via a

pressurized metered dose inhaler (see [0014]). The suitable particle size for the said particles are 5 micron or less (see [0018]).

Claims 1, 5, 7, 11-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Nguyen et al (US 20040081624 A1).

Nguyen et al discloses liquid aerosol formulations and aerosol generating devices and for generating aerosols. Various active agents can be used in the said aerosol formulations. Examples include medicaments for treating erectile dysfunction such as sildenafil, vardanafil, apomorphine, yohimbine, etc (see [0045]). Other medicaments include testosterone, estrogens, estradiol, etc (see [0055]). The particle size suitable for the said formulations is in the range of 0.5 to 2.5 microns (see [0083]).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 11-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-29 of U.S. Patent No. 6,632,419. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. That is claims 1-7 and 11-18 are generic to all that is recited in claims 22-29 of U.S. Patent No. 6,632,419. That is, claims 22-29 of U.S. Patent No. 6,632,419 fall entirely within the scope of claims 1-7, 11-18. Specifically, the method of treating erectile dysfunction in a patient comprising aerosolizing a formulation comprising sildenafil, and a kit comprising a device and the said formulations are the same as the methods and kits disclosed in the reference claims. The only difference is that the reference claims are drawn to a composition comprising the specific salt of sildenafil citrate, whereas the instant claims are broader in scope and claim sildenafil. Claims 7 and 15 are drawn to a method and a kit comprising a formulation comprising an active agent selected form the group consisting of PDE5 inhibitor, dopamine receptor agonist, a melanocortin receptor agonist, etc. Reference claims are to formulations comprising sildenafil, which is a PDE5 inhibitor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mina Haghighatian
February 17, 2005